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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,105	07/22/2003	Takashi Tsuji	14539-006002	8893
26161	7590	05/03/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,105

Applicant(s)

TSUJI ET AL.

Examiner

ILIA OUSPENSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 109 and 113-213 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 109, 113, 114, 121-148 and 152-213 is/are allowed.
- 6) ☒ Claim(s) 115 - 120 and 149 - 151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments/remarks, filed 02/14/2006, are acknowledged.

Claims 110 – 112 have been cancelled.

Claims 1 – 108 have been cancelled previously.

Claims 109, 113, and 114 have been amended.

Claims 180 – 213 have been added.

Claims 109 and 113 – 213 are pending.

2. This Office Action will be in response to applicant's amendment and arguments, filed 02/14/2006.

The rejections of record can be found in the previous Office Action, mailed 11/15/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

- 3. *The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.***

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4. Applicant's amendment to change the Title is acknowledged. However, the new title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

The following title is suggested: METHODS OF TREATING AN INFLAMMATORY DISORDER WITH AN ANTIBODY AGAINST COSTIMULATORY SIGNAL TRANSDUCTION MOLECULE AILIM.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 118 – 120 and 149 – 151 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 118 – 120 and 149 – 151 are indefinite in the recitation of "a V region DNA encoding a heavy (or light) chain variable region," because the recitation lacks antecedent basis in the respective base claims 109 and 115. Therefore, one of ordinary skill in the art would not be reasonably apprised whether the recitation refers to the V region DNA encoding the heavy (or light) chain variable region of claims 109 and 115, respectively.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

7. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 115 – 117 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting production of IFN γ or IL-4, does not reasonably provide enablement for a method of inhibiting production of a generically recited “cytokine.” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification discloses that the claimed methods are effective in inhibiting production of IFN γ or IL-4 (e.g. Example 8 at pages 117 – 122), and also in reducing inflammation (e.g. claim 109). However, a person of skill in the art at the time the invention was made was aware that the recited genus of “cytokines” encompasses, among others, anti-inflammatory cytokines, such as IL-10 (see e.g. Chaouat et al., J. Immunol., 1995, vol. 154, pp. 4261-4268; in particular page 4261, first paragraph).

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Therefore, Applicant has not provided a sufficiently enabling disclosure regarding how to inhibit the production of any cytokine with the claimed antibody.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the identity of cytokines which may be inhibited by the claimed anti-AILIM antibodies is unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

9. Conclusion: claims 109 and 113, 114, 121 – 148, and 152 – 213 appear to be allowable.

The claims appear to be free of prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

May 1, 2006


PHILLIP GAMBEL, PH.D J.D.
PRIMARY EXAMINER
TC1600
5/1/06